भारतीय मानक
Indian Standard

IS 17715 : 2023

इन-विट्रो डायग्नोस्टिक (आईवीडी) उपकरण — एलिसा प्लेट वॉशर

In-vitro Diagnostics (IVD) Device — ELISA Plate Washer

ICS 11.100.10

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भारतीय मानक ब्यूरो
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November 2023 **Price Group 4**

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the *In-vitro* Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee had been approved by Medical Equipment and Hospital Planning Division Council.

This standard describes the performance qualification requirements of ELISA plate washer intended for *in vitro* diagnostic use. The instrument is intended for use by qualified personnel, for the designed purposes under specified conditions, following proper procedures and safety rules.

The composition of the Committee responsible for formulation of the standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed, or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

IN-VITRO DIAGNOSTICS (IVD) DEVICE — ELISA PLATE WASHER

1 SCOPE

This Standard provides the performance qualification requirements of ELISA plate washer intended for *in-vitro* diagnostic use.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards.

IS No.	*Title*
IS/ISO 13485 : 2016	Medical devices — Quality management systems — Requirements for regulatory purposes (*first revision*)
IS/ISO 14971 : 2019	Medical devices — Application of risk management to medical devices (*first revision*)
IS 17724	Safety requirements for electrical equipment for measurement, control, and laboratory use:
(Part 1) : 2023	General requirements
(Part 4) : 2023	Particular requirements for *In-vitro* diagnostic IVD medical equipment
IS 17784	Electrical equipment for measurement, control and laboratory use — EMC requirements
(Part 1) : 2023	General requirements
(Part 2) : 2023	Particular requirements for *In-vitro* diagnostic (IVD) medical equipment

3 TERMS AND DEFINITION

3.1 ELISA Plate Washer

This is a general-purpose laboratory instrument used to automate the procedure of washing the ELISA samples arranged in plate-based format by dispensing, soaking and aspirating the cleansing liquid into and from the manifold or wash head.

3.2 Optical Density (OD)

Optical density measures the speed of light while passing through an optically dense medium. It is defined as the logarithmic ratio of the intensity of incident light (I_o) to the intensity of the transmitted light (I_t) passing through that medium.

$$\text{Optical Density (OD)} = \log_{10} \frac{I_0}{I_t}$$

4 PRINCIPLE

4.1 The ELISA plate washer supplies the required washing buffer into the wells from the dispensing needle of the wash head or the manifold. The washing buffer is soaked or agitated based on the programming. The unbound reagents are removed based on the time set, through the aspirating needle.

4.2 Wash head can have 8 channels to 12 channels with dual pins called dispensing needle and aspirating needle.

4.3 The ELISA plate washer consists of two reservoirs; one for the washing buffer and the other for the waste generated during the washing process.

4.4 The device shall be programmable for operation in different modes, range of volumes, time duration of rinsing and number of cycles of wash.

5 GENERAL REQUIREMENTS

5.1 Electromagnetic Compatibility Requirements

The ELISA plate washer shall comply with the requirements as specified in IS 17784 (Part 1) and IS 17784 (Part 2).

5.2 Electrical Safety Requirements

The ELISA plate washer shall comply with the requirements as specified in IS 17724 (Part 1) and IS 17724 (Part 4).

6 PERFORMANCE MEASUREMENT AND QUALIFICATION PROCEDURE

6.1 Wash Volume/Dispense Precision Test

6.1.1 Wash volume or the dispense precision test is a measure of the variability of volumes dispensed across the manifold.

6.1.2 *Procedure for Quantifying the Wash Volume*

6.1.2.1 300 µL of dye solution of known optical density is dispensed into the plate washer. The optical density across the manifold is measured. The optical density is proportional to the total volume of liquid. The mean of optical density, standard deviation and percent coefficient of variation are calculated. The percent coefficient of variation shall be less than 3 percent for 300 µL of solution.

6.2 Residual Volume/Evacuation Efficiency Test

6.2.1 The washer evacuation efficiency test measures the residual volume.

6.2.2 *Procedure for Measuring the Residual Volume*

6.2.2.1 Known deionized water or buffer solution is aspirated into the ELISA plate of known weight. Weight of the plate is measured again. The difference in the weight is calculated. The residual volume is calculated from the weight difference. The mean residual volume is calculated. The value of the mean residual volume shall be less than 2 µL per well.

7 RISK MANAGEMENT AND QUALITY CONTROL

7.1 The device shall comply with IS/ISO 14971 and apply the risk management process for the device.

7.2 The manufacturer of the device shall comply with the quality management system standard IS/ISO 13485.

8 OPERATING MANUAL

The device shall be accompanied with the operating manual with the following information:

a) Instructions for installation;
b) Manual for operation of the device; and
c) Routine maintenance and service procedure.

9 MARKING, LABELLING AND PACKAGING

9.1 The device shall be legibly and indelibly marked at suitable place with the following details:

a) Name of the manufacturer and address;
b) Country of manufacture;
c) Serial number; and
d) Warning labels.

9.2 The device shall be packed securely with suitable material, to ensure that the risk of damage is minimized during the transportation.

9.3 Proper decontamination procedure shall be followed before packing the device.

9.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

Organization	*Representative(s)*
In Personal Capacity (*E117 first floor Greater Kailash 2, New Delhi, 110048*)	Dr Reba Chabbra **(*Chairperson*)**
ADMI (Association of Diagnostics Manufacturers of India)	Ms Veena Kohli
Abbott Healthcare India Private Limited, Mumbai	Shri Jaya Sunil Lande Dr Asok Kumar Raghvan Nair (*Alternate*)
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AIIMS, Bilaspur	Dr Anurag Sankhyan
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Association Of Indian Medical Device Industry, New Delhi	Shri Abhijeet Singhvi Shri Jatin Mahajan (*Alternate*)
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BIOMERIEUX, New Delhi	Shri Bivash Chakraborty
Bio-Rad Labs India Pvt Ltd, Gurugram	Ms Divya Vohra Shri Alok Kumar Soni (*Alternate*)
Boston Scientific India Private Limited, Gurugram	Ms Kirti Arora Ms Preety Sharma (*Alternate*)
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Indian Council of Medical Research, New Delhi	Dr Chander Shekhar

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